Instituting an Office-Based Surgery Program in the Gynecologist’s Office

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Instituting an Office-Based Surgery Program in the Gynecologist's Office

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ABSTRACT Office-based surgery (OBS) provides many advantages for the patient, physician, operating room team, and health care system. Newer technologies provide an array of procedures appropriate to the office setting, and with careful preparation, many can be performed without compromising patient safety or comfort. Several states have specific regulatory requirements for OBS, although half of them provide neither guidelines nor regulation. The Federation of State Medical Boards provides current regulatory information across the United States; the American College of Obstetrics and Gynecology has recently issued guidelines that provide recommendations for instituting an OBS practice, and the American Medical Association and the American Society of Anesthesiologists provide guidelines that promote patient safety and comfort in the office setting. Many issues must be considered before instituting an OBS program. Practices that perform invasive procedures requiring more than minimal sedation are encouraged to seek formal accreditation because it assures patients of quality of care. Residency programs and professional societies are encouraged to provide training in OBS surgery and to develop programs to mentor the next generation of physicians. Journal of Minimally Invasive Gynecology (2010) 17, 673-683 © 2010 AAGL. All rights reserved.

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In the last 40 years, a variety of gynecologic procedures have been successfully performed in an office setting. These include first- and second-trimester abortions [1], dilation and curettage [2], diagnostic hysteroscopy [3-5], operative hysteroscopy [6], tubal sterilization via laparoscopy [7] and minilaparotomy [8], laparoscopic pain mapping [9,10], and large-loop excision of the transformation zone procedures [11]. Recent technologic advances now enable an increasing number of office-based procedures including nonresectoscopic endometrial ablation [12-14], and hysteroscopic tubal occlusion [15,16]. The advantages of office based surgery (OBS) include greater cost savings to the healthcare system and substantial benefits for the patient, gynecologist, and operating team.

For the patient, the benefits include familiar surroundings, simplified scheduling, care from familiar staff, less time in a medical facility, and less invasive methods of pain control. For the gynecologist, the benefits include easier scheduling, greater control over all aspects of intraoperative and perioperative care, more efficient use of time, and immediate availability during all phases of recovery. In addition, the physician may benefit from increased reimbursement for specific procedures performed in an OBS setting.

There are also potential advantages for the office operating room (OR) crew including circulating nurses, scrub technicians, sonographers, post-anesthesia nurses, and assistants. Their small number and work with fewer physicians performing a limited number of office procedures facilitates greater expertise. With appropriate leadership, the relative agility of the office OR crew may be better positioned to reduce human error. Several authors [17-21] have suggested that the aviation model of crew resource management (CRM) [22] be adopted in an OR to reduce errors. This paradigm, which stresses the importance of leadership, interpersonal communications, and decision making, originated in 1979 as a response to a National Aeronautics and Space
Administration workshop that examined the role of human errors in commercial air crashes. The healthcare industry began to investigate aviation CRM after the Institute of Medicine report, "To Err is Human: Building a Safer Health Care System" [23], recommended that medicine adopt aviation's approach to safety and error management. The office, with its smaller size and scope of procedures, and limited layers of administration may be an ideal setting for CRM principles to evolve and take root. The office OR crew exerts greater control over its equipment use and care, use of individualized operating room checklists [24], and rapid development of specific policies and procedures designed to improve outcomes.

This article reviews the recent history of OBS, the regulations and policies that affect OBS across the United States, and the various gynecologic procedures that can be incorporated into an office-based practice. In addition, it addresses some basic considerations in implementing an OBS program.

History of OBS in Gynecology

Gynecology has deep roots in OBS. As states began to legalize abortion in 1967, the need for efficient and confidential office-based procedures became evident. The office provided greater privacy, cost containment, and individualized care in a controlled environment staffed by supportive and knowledgeable professionals. Physicians soon began considering other possible applications for OBS. Penfield [2] observed "how logical and easy it was to add sterilization to abortion services, particularly because we continued to perform all operations under local anesthesia."

In 1977, Penfield [7] reported on 1200 office-based laparoscopic tubal fulgurations performed with the patient under local anesthesia augmented by oral and intravenous sedation, and in 1979, he reported the results of 200 sterilizations performed at minilaparotomy [8]. In 1989, Mehta [25] reported the results of more than 250,000 laparoscopic sterilizations performed in ad hoc "sterilization camps" in Bombay, India, all performed with the patient under local anesthesia using Falope rings. Palter [9] and Palter and Olive [10] reported on the use of office-based laparoscopy as a diagnostic tool for evaluation of chronic pelvic pain. Other office innovations include large-loop excision of the transformation zone [11], which has largely replaced the traditional cone biopsy and enables effective office treatment of many cervical intraepithelial neoplasias.

Diagnostic hysteroscopy has long been advocated as an office-based procedure. It is most commonly used in evaluation of abnormal uterine bleeding [26–28], but has an important role in various other clinical settings including infertility and recurrent pregnancy loss, pre--in vitro fertilization evaluation, and assessment of the abnormal hysterosalpingogram [29,30]. In 1996, Isaacsen [31] noted that only 8% of gynecologists routinely perform office hysteroscopy. This number will likely grow as in-office hysteroscopic tubal occlusion supplants many laparoscopic sterilization procedures.

In the early 1990s, newer rigid hysteroscopes were introduced, accompanied by operative sheaths with an outside diameter less than 5 mm. Betocchi et al [32] reported their results of 4863 procedures performed in an office setting, demonstrating that diagnostic and operative hysteroscopy can often be combined ("see and treat" approach), producing excellent outcomes with a high degree of patient satisfaction in women with small and benign lesions. In that series, a 5F operating channel was used, along with mechanical scissors and graspers to remove polyps ranging in size from 0.2 to 3.7 cm, and intrauterine adhesions. In another series of 501 patients, Betocchi et al [33] reported the use of the Gynecare VersaPoint Bipolar Electrosurgical System (Ethicon, Inc., Somerville, NJ), which enabled removal of polyps ranging from 0.5 to 4.5 cm and myomas ranging from 0.5 to 2 cm.

Until recently, the effect of OBS on our specialty has been limited. However, the introduction of simplified techniques for endometrial ablation and tubal occlusion in a fiscal environment that often encourages OBS may foster substantial growth in the number of office-based procedures.

In 1997, the first nonresectoscopic endometrial ablation device (Gynecare ThermaChoice Uterine Balloon; Ethicon, Inc.) was introduced. This method has been used in both hospital- and office-based settings, with acceptable results [34]. In 2001, the US Food and Drug Administration (FDA) approved 2 additional devices for nonresectoscopic endometrial ablation, the NovaSure System (Hologic, Inc., Palo Alto, CA) [35,36] and the HydroThermAblator System (Boston Scientific Corp., Natick, MA) [37,38]. Two other office-based devices include the Her Option Uterine Cryoablation Therapy System (American Medical Systems, Minnetonka, MN) [39] and the Microwave Endometrial Ablation System (Microsulis Medical Ltd., Denmead Hampshire, Hampshire, England) [40]. All of these devices have been successfully used in an office setting, with a variety of analgesic protocols.

In 2002, the Essure Contraceptive System (Conceptus Inc., Mountain View, CA) [41,42] received FDA approval, ushering in a new era of hysteroscopic tubal occlusion (HTO). In 2009, the Adiana system (Hologic, Inc.) [43,44] also gained FDA sanction, providing another office-based HTO method. Before introduction of HTO, the criterion standard for interval sterilization had been a laparoscopic approach using mechanical clips, rings, or thermal energy. The present HTO technology seems to support the claims of improved efficacy and safety, and decreased pain and cost [45,46]. These methods, ideally suited for an office setting, may well emerge as the new criterion standard for female sterilization.

As the movement toward OBS procedures has gained momentum, greater regulation has accompanied its growth. While the licensing of technology is federally regulated by the FDA, its implementation, whether in a hospital,
ambulatory surgical center, or office, is regulated by the individual states. Only recently, in January 2010, did the American College of Obstetricians and Gynecologists issue guidelines for OBS [47], thereby establishing a national practice standard.

Regulations and Policies that Govern OBS Across the United States


While physicians embraced the advances in OBS, the media, state-elected officials, and state regulatory agencies were less than enthusiastic. In 1998, in response to a number of well-publicized stories about deaths and patient injury resulting from office surgeries, the Florida Board of Medical Examiners revisited its "Rule of Administrative Procedures" that governed physicians' standard of care in office procedures. In Florida in March 2000, a statute (FL Stat 458.351) took effect, requiring the reporting of adverse outcomes in an office setting. After receiving the first incident reports, the Florida Board of Medical Examiners issued a 90-day moratorium on all level-III office-based surgeries, that is, those requiring general or major conduction anesthesia. In the September 17, 2000, edition of the Chicago Sun-Times, the medical editor of WBBM Channel 2 in Chicago, Illinois, noting the recent moratorium on OBS in Florida, opined, "You're likely to get your next operation right in your doctor's office; and you may be putting your life on the line as a result" [49]. That same week New York's Newsday published a report on the adverse outcomes, and even deaths, resulting from the increasing number of, mostly cosmetic, OBS procedures [50]. Quattrone [51] went so far as to describe surgery in the physician's office as the "wild, wild west of health care."

Yet by 2001, only 6 states (California, Florida, New Jersey, Pennsylvania, Rhode Island, and Texas) had laws or regulations for OBS. Junco et al, [52] in their 2002 "Report of the Special Committee on Outpatient (Office-Based) Surgery," noted that offices have not been "subject to the same state and federal licensing requirements as hospitals and other health care facilities, making it relatively easy to open an office-based surgical practice."

At present, there exists a patchwork quilt of regulations across the United States. As of this writing, 9 states (Connecticut, Indiana, Ohio, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, and South Carolina) require accreditation once various thresholds have been crossed. Twenty-five states (Alaska, Arkansas, Delaware, Georgia, Hawaii, Idaho, Iowa, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming) and Guam and Puerto Rico have no requirements for OBS or office-based anesthesia. Of the remaining 16 states and the District of Columbia, the following standards exist [53]:

- **Alabama**: In November 2003, the Alabama State Board of Medical Examiners adopted rules on OBS, requiring physicians who maintain OBS practices to register with the Board. The rules list requirements for office setting, equipment, supplies, maintenance of medical records, security, reporting of specific events, and emergency transfer planning.
- **Arizona**: As of January 2008, the Arizona Medical Board requires a health care institution license for physicians who provide general anesthesia in their office, qualifying standards for staff members, space and equipment requirements, and sedation monitoring standards.
- **California**: California passed enabling legislation in 1999; the Act requires a report to the State Medical Board of any procedure carried out in a nonhospital setting that results in a death or a transfer to a hospital or emergency center within a specified time. The legislation specifies minimum staffing requirements, and requires Medicare certification or accreditation for all outpatient facilities administering anesthesia other than local anesthesia or nerve blocks. The Division of Licensure recognizes the Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), and Joint Commission for Accreditation of Healthcare Organizations (JCAHO) as approved accrediting agencies.
- **Colorado**: In 2001, the Colorado Board of Medical Examiners adopted Policy Statement 40-12. The policy disallows certain procedures in an office setting, and recommends that a surgeon have staff privileges at a licensed hospital to perform any procedure in an office. The policy also requires a written transfer agreement in place, between an OBS and a hospital, for emergency purposes, and guidelines for supervision of qualified anesthesia providers.
- **District of Columbia**: In 2000, the District of Columbia Board of Medicine issued an advisory that it would follow guidelines issued by the American Society of Anesthesiologist (ASA), the requirement for a medical director and standards for OR personnel. In addition, facility standards, minimum equipment requirements, and emergency transfer protocols were also specified.
- **Florida**: In March 2002, the Florida Medical Board adopted Standards of Care for Office Surgery 64BB9.009. These rules provide a definition of OBS, and specify levels of surgery along with general requirements for OBS. The rules adopted the ASA "Standards for Basic Anesthesia Monitoring," and specify requirements and qualifications for anesthesia providers. The rules also specify requirements for surgical training, equipment and supplies, and emergency transfer agreements. Requirements
for surgeons, anesthesia providers, and the surgical setting vary according to the level of surgery. Florida law also requires inspections of OBS facilities by the Department of Health or by a nationally recognized accrediting agency approved by the Board.

• Illinois: In 2002, Illinois passed regulations, Rules for the Administration of Medical Practice Act 1285.340, delineating requirements for anesthesia services in an office setting. The surgeon, anesthesiologist, and certified registered nurse anesthetist are required to have current advanced cardiac life support (ACLS) certification.

• Kansas: Effective in August 2005, Kansas rules establish requirements for OBS that address personnel, equipment, administration of anesthesia, and administrative policies and procedures. The standard of care is established by the regulations enumerated in Article 25.

• Kentucky: The Board adopted guidelines in 2003 that differentiate level I, II, and III offices based on the types of procedures performed and associated levels of sedation or anesthesia required for these procedures. Level II and III facilities should be accredited by a recognized authority. Provisions encourage implementation of policies and procedures for emergency care and transfer planning, infection control, performance improvement, reporting of adverse incidents, and compliance with federal and state laws and regulations.

• Louisiana: State rules require that physicians performing OBS procedures have current staff and admitting privileges at a hospital located within a reasonable proximity to the facility, and have achieved certification from a member board of the American Board of Medical Specialties in a specialty that encompasses the office-based procedure. In addition, ACLS certification is required. Procedures must be of a nature that enables a patient to be discharged from the facility on the same day. Emergency transfer policies must be in place, along with specific requirements for anesthesia administration and monitoring. Specified complications must be reported to the Board within 15 days.

• Massachusetts: The Medical Board endorsed the Massachusetts Medical Society OBS Guidelines of December 2000 and September 2004. The guidelines propose minimum standards for 3 classifications of office settings based on the level of anesthesia and complexity of the surgery. The guidelines recognize published ASA guidelines, and address patient admission and discharge, office administration, emergency care and transfer to hospitals, management of medical records, administration of anesthesia, infection control policies, performance measurement, report of adverse incidents, patient bill of rights, and compliance with federal and state regulations. In addition, training of other health care personnel, facility accreditation, and minimum standards for equipment and supplies are specified.

• Mississippi: Office-based surgical procedures are designated as level I, II, or III, with associated requirements related to the scope of permitted procedures to be performed. The rules also address levels of anesthesia, training for health care personnel, equipment and supplies, policy and procedure manuals, reporting of adverse incidents, and a written response plan for emergencies. In addition, it states standards for sterilization of instruments and maintenance of medical records, and requires that all level I, II, and III surgical procedures be logged.

• North Carolina: The North Carolina Medical Board provides guidelines for OBS procedures that require physicians to be credentialed to perform the same procedure by a hospital or ambulatory surgery center. After 1 year of operation, any physician who performs level II or III procedures in an office should be able to demonstrate substantial compliance with the guidelines or should obtain accreditation by an approved accreditation agency. Certain complications require a report to the Medical Board.

• Oklahoma: The Oklahoma State Board of Medicine adopted guidelines in 2002 for physicians who perform ambulatory surgery and other invasive procedures that require anesthesia or sedation in an OBS setting. Physicians who perform OBS are required to address issues of quality of care, facility maintenance, patient and procedure selection, preoperative care, monitoring, equipment, and emergency transfer protocols.

• Tennessee: The OBS rule 63-6-221 states that “the Board will always judge the decision to perform surgery in the office setting based upon what was in the patient’s best interest and through strict application of these rules.” The rules list various governmental requirements for OBS.

• Texas: The rules require that physicians who perform surgical procedures using anesthesia in an outpatient setting report annually with the Board. The rules apply to an outpatient setting that is not part of a hospital or ambulatory surgical center and in which general, regional, or monitored anesthesia is required.

• Washington: The Washington State Medical Association Medical Quality Assurance Commission references the Federation of State Medical Boards (FSMB) “Guidelines for Office-Based Surgery, 2002,” which adopts a 3-level approach based on levels of sedation, analgesia, and general anesthesia used. The Quality Assurance Commission defines OBS, physical status of patients based on degree of anesthesia risk, levels of sedation, and related terms. The provisions address governance of the facility, national accreditation as evidence of achievement of acceptable standards, emergency care and transfer planning, personnel, credentialing of physicians, maintenance of medical records, patient bill of rights, anesthesia equipment, infection control policy, reportable incidents, and performance improvement.

Clearly, the last decade has seen an increasingly active role by state medical boards responding to consumer demand for greater accountability in an office setting. In April 2001, the Federation of State Medical Boards formed
a special committee on outpatient (office-based) surgery [52]. The Federation House of Delegates adopted the committee recommendations as policy in April 2002. This model includes recommendations on administration, personnel, patient evaluation, anesthesia, accident reporting, facilities accreditation, and liposuction procedures [53]. It is reasonable to expect that the current trend will continue and that gynecologists would be well advised not only to comply with their local and state regulations governing OBS practice, but to respond proactively to what will likely be an increasingly regulated environment.

In response to the inconsistency of state laws and because many states do not regulate OBS, in 2010, the American College of Obstetricians and Gynecologists published its "Executive Summary for the Presidential Task Force on Patient Safety in the Office Setting" [47]. The Task Force recommendations are extensive, and are designed "to assist, inform, and enable Fellows to design and implement processes that will facilitate a safe and effective environment for the more invasive technologies currently being introduced into the office." The Task Force encourages gynecologists to provide systems that will provide the same level of safety for patients regardless of where they seek treatment.

The Task Force notes that many "low tech" lessons and tools readily associated with the inpatient setting culture, organization, and infrastructure can also be easily implemented in the office; among these are, leadership, competency and assessment, teamwork and communication, checklists, times out and drills. These "lessons" form the foundation of the aviation industry CRM [23]. Additional recommendations of the Task Force are shown in Fig. 1 in the form of a 7-step program that should serve as a template for immediate change expected in offices that provide increasingly invasive procedures.

Physicians who incorporate moderate sedation–analgesia, deep sedation–analgesia, or general anesthesia in an office-setting should consult the "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" [54] and the AMA Core Principles for Office-Based Surgery" [55]. These guidelines and principles represent an important national standard that has been used by all of the major national accreditation institutions and many state governments.

For physicians whose practice includes procedures that may be considered invasive (e.g., laparoscopy, operative hysteroscopy excluding tubal occlusion, and liposuction involving removal of >500 mL of fat), voluntary accreditation by one of the nationally recognized agencies is available even if it is not required in your locale. Facilities can be accredited by the AAAASF, the AAAHC, the JCAHO, the American Osteopathic Association (AOA), or a state-recognized entity such as the Institute for Medical Quality (IMQ). Some states require state-licensed or Medicare certification.

Gynecologic Procedures Appropriate in an Office-Based Practice

My practice is located in Rochester, New York, a state that requires formal accreditation for OBS practices that perform more than "minor" procedures or offer more than "minimal sedation" as defined under New York State Public Health Law, §230-d [56]. Our OBS practice includes basic hysteroscopic procedures including diagnostic hysteroscopy, tubal occlusion, lysis of intrauterine synechiae, and removal of uterine septae, polyps, and small (≤2 cm) myomas. We offer advanced hysteroscopic procedures that include ultrasound-guided endomyometrial resection, removal of medium and large submucous and intramural myomas, and repeat hysteroscopic surgery for endometrial ablation and resection failures. I also manage pregnancy failure, perform first- and second-trimester abortions, large-loop excision of the transformation zone procedures, and incision and drainage of the Bartholin gland and other vulvar abscesses, as well as marsupialization of Bartholin gland cysts.

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**Summary of ACOG Guidelines for initiating an Office-Based Surgery Program**

1. Designate a medical director with specific patient safety responsibilities
2. Create a specific short training manual for all office staff.
   a. Import local hospital and ambulatory surgery center documents already available.
   b. Contact state and other regulatory bodies for requirements that must be met in your locale.
   c. Make this document available and mandatory, with sign-offs by all staff.
3. Create a mock drill and try one.
4. Create a checklist for one procedure and follow it closely; revise as indicated.
5. Survey and certify staff. (Who has Basic Life Support or Advanced Cardiac Life Support training?)
6. Carefully reexamine anesthesia methods and compare with published guidelines.
7. Discuss patient safety goals with each patient to create a safer environment for the procedure.

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Fig. 1. Summary of ACOG guidelines. From [47].
### Gynecologic procedures that can be done in an Office-Based Surgery Setting

**Uterus**

- **Diagnostic Hysteroscopy with or without curettage**
- **“Minor” Hysteroscopic Surgery**
  - Tubal occlusion—Essure, Adiana
  - Polypectomies (less than 2 cms)
  - Myomectomies (less than 2 cms) and submucous (type 0)
  - Retrieval of “lost” intrauterine devices
- **“Major” Hysteroscopic Surgery**
  - Endometrial ablation, Transcervical Resection of the Endometrium (TCRE)
  - Myomectomies (greater than 2 cms), type 1 or completely intramural
  - Division of uterine septum
  - Reoperative hysteroscopy
- **Lysis of intrauterine synechiae**
- **Non-resectoscopic endometrial ablation (“Global”)**
  - Thermal balloon
  - NovaSure
  - Hydrothermal ablation
  - Cryoendometrial ablation
  - Microwave endometrial ablation

**Pregnancy Terminations and Pregnancy Failure**

- 1st trimester
- 2nd trimester (13.0 – 20.0 weeks)
- Suction curettage

**Cervix**

- LLETZ procedures

**Vulva and vagina**

- Biopsies
- Bartholin’s gland abscess (incision and drainage)
- Bartholin’s gland marsupialization
- Imperforate Hymen
- Vaginoplasty, Labioplasty

**Laparoscopy**

- Pain mapping
- Laparoscopic sterilization procedures

**Urogynecology**

- Transvaginal tape procedures (TVT)

**Infertility**

- Sonographically-guided oocyte retrieval for IVF

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I have 30 years of experience with conscious sedation, and have performed more than 45,000 procedures. The list of other procedures appropriate for a properly trained physician and OR crew in a well-ordered OBS setting is extensive (Fig. 2), and includes laparoscopic pain mapping [9], global endometrial ablation [12,13,38] [Woods MP, University of Nebraska Medical Center, personal communication, March 18, 2010], and even vaginal sling procedures [59]. It may be anticipated that future technology will enable an increasing number of procedures to be safely performed in an office setting.

Appropriate OBS procedures must have manageable risk and be accompanied by a suitable level of anesthesia. The executive summary of the ACOG Task Force on Office-Based Surgery clearly states that “The decision regarding type of anesthesia should not be altered based on limitations of equipment or personnel in the office setting; rather, it should be based on patient needs in relation to the planned procedure” [47].

The role of adequate analgesia deserves special attention. Numerous studies cast significant doubt that even simple hysteroscopic procedures can be performed under paracervical block (PCB) without supplemental analgesia or sedation. Two studies, by Bradley and Widrich [60] and Readman and Maher [61], demonstrate that diagnostic hysteroscopy performed without supplemental analgesia or sedation was intolerable in 3.6% and 10% of patients, respectively. In a third study, Lau et al [62] compared use of 2% lignocaine vs saline solution in women undergoing hysteroscopy and biopsy. They concluded that PCB failed to attenuate the pain associated with hysteroscopy, citing that the injection itself is painful and associated with some risk. Similar results have been found by several authors who studied the usefulness of PCB in hysteroscopic tubal occlusion. Chudnoff et al [58] analyzed 80 women who underwent HTO, and observed that PCB reduced pain only for cervical dilation, but did not attenuate pain related to uterine distention and device placement. Similar results were reported by Lopes et al [63].
The authors concluded that "given how widely used the PCB is, the paucity of data supporting the benefit of a PCB as shown in this review is surprising and concerning." One must be concerned that practices considering OBS procedures that involve diagnostic hysteroscopy, tubal occlusion, endometrial ablation, and instrumentation of the uterine walls consider protocols that provide sufficient analgesia or sedation to accomplish these procedures while not compromising patient comfort.

Without the availability of some form of effective sedation and analgesia, the gynecologist will not only have to carefully select patients for a given procedure, but accept the consequences of guessing incorrectly, and either halt a procedure before its completion or provide an unsettling experience for the patient, physician, and staff. As a matter of practicality, it will be difficult to establish an OBS practice if a patient reports to her referring physician and friends that she had an unacceptable experience. Use of effective analgesics and sedatives often averts the dilemmas that accompany unanticipated intraoperative pain and anxiety.

Physicians are often cowed by the use of conscious sedation in their office practice, fearing a cardiorespiratory arrest in a setting lacking the support staff customary in a hospital OR or ambulatory surgical center. In reality, respiratory arrest occurs rarely, and is more likely in an elderly population of patients in whom high dosages are combined with opiates. In a study by Classen et al [64] in which 5439 patients were given midazolam, respiratory arrest occurred in 3 (0.10%); all were elderly and received high dosages of midazolam in combination with an opiate. All of the patients responded to prompt treatment, and survived. Conscious sedation protocols can be carefully incorporated into an office setting, but require strict adherence to state regulatory requirements [53], practice guidelines issued by the ASA [54], the AMA Core Principles of Office-Based Surgery [55], the ACOG Task Force on Office-Based Surgery [47], and any organizations that provide accreditation or licensing for a medical practice.

Although the introduction of moderate conscious sedation in an office-based practice is a serious and time-consuming undertaking, many physicians wrongly assume that use of parenteral agents is contraindicated in a minimal sedation program. This often deprives the patient of a preferable pharmacologic effect, a precisely controlled short-acting sedative and analgesic that produces sufficient peak serum levels during a procedure rather than longer-acting oral medications that generate imprecise and inadequate serum levels that may peak well after the patient has left the office. It is noteworthy that the definitions of various levels of sedation do not depend on either the type of medication used or its route of administration [54,55], but on the effect of a particular drug or combination of drugs. Many physicians who would like to limit their practice to use of minimal conscious sedation may often do so without crossing a threshold that requires them to seek formal credentialing or licensing, simply by careful titration of parenteral agents. Successful office-based gynecology practices are able to provide appropriate procedures without compromising patient safety or comfort.

Considerations in Implementing an OBS Practice

Implementation of an OBS practice depends on a variety of considerations (Fig. 3) including community need; financial viability of such a plan; ability to effectively lead its development and oversee its quality improvement; proper selection of procedures; availability of appropriate analgesia, sedation, or anesthesia; and a variety of regulatory, liability, staff, and policy and procedure considerations.

Financial Considerations

A viable OBS practice must begin with a fundamental business plan. Some plans can be rudimentary. Many practices now perform HTO as an office procedure. In recent years, some device manufacturers have offered physicians economic incentives in the form of hysteroscopy and video equipment in exchange for a guaranteed minimum number of procedures per year. With careful patient selection, many HTO procedures can be performed with the patient under level 1 anesthesia (minimal sedation or anxiolysis) [54]. The ASA [65] and ACOG [47] guidelines require personnel with training in basic life support and emergency equipment for cardiorespiratory support and treatment of anaphylaxis. Therefore, a practice large enough to meet contractual demands for device purchases may require only a limited financial investment. Costs increase with levels of complexity, invasiveness, and need for deeper levels of sedation, and should be anticipated in practices that perform advanced hysteroscopic procedures, nonresectoscopic endometrial ablation, oocyte retrieval, and invasive cosmetic procedures. Beyond the substantial investment in capital equipment, the cost of compliance with state regulatory processes must be considered. Formal accreditation by a nationally recognized agency, even if not a local requirement, is strongly advised for offices that perform more invasive procedures under deeper levels of sedation, analgesia, or anesthesia. Specific financial considerations that must be addressed in developing a business plan are shown in Fig. 3.

Leadership, Training, and Competence

The ACOG, numerous state health departments, and all major national accrediting institutions require the identification of a medical director. The medical director, in addition to having an important administrative role in adhering to guidelines developed by ACOG (Fig. 1), sets the tone of the organization with respect to patient safety, staff development, and implementation of policies and procedures in
### Considerations in Implementing an Office-Based Surgery Program

#### I. Financial Considerations
- Is there a community need?
- What are the specific procedures being proposed?
- What are the costs of renovation of existing space to comply with state regulations?
- What are the costs of capital equipment?
  - Procedure specific equipment as well as redundant equipment
  - Anesthesia-related equipment (oxygen monitoring equipment and automated blood pressure and recording equipment)
  - Emergency Equipment (defibrillator, emergency cart, EKG machine) and cart standby generators
- What is the estimated cost of equipment maintenance and inspections?
- Is there an economic advantage from local insurers?
- Is there an economic advantage related to improved efficiency?
- Is there a requirement for formal accreditation or licensing?

#### II. Leadership, training and competence
- Do you have a qualified medical director as required by ACOG and numerous nationally recognized accrediting agencies?
- Do you or members of your group possess the necessary and appropriate training and skills to deliver the proposed services?
- Does the physician have admitting and similar operating privileges at a nearby hospital?
- Is someone available for adequate peer review?
- Do you plan on obtaining ACLS certification or credentialing for conscious sedation?

#### III. Anesthesia Considerations
- Is the proposed anesthesia and analgesia/sedation appropriate to the anticipated procedures without compromising patient safety or comfort?
- What are the levels of sedation/analgesia anticipated?
- Do you have an anesthesia screening tool as recommended by ASA?

#### IV. Emergency Transfer Plan
- Can you evacuate a patient in a timely fashion to a nearby emergency facility in a timely fashion?

#### V. Mechanism of continuous quality improvement

#### VI. Staff considerations
- Appropriately licensed and trained personnel (BLS, ACLS, Conscious sedation)
- Survey and certify staff (ACOG recommendation)
- Enthusiasm and support
- Do you plan on implementing CRM training for your office OR staff?

#### VII. Patient Selection

#### VIII. State and local zoning requirements

#### IX. Liability

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Fig. 3. Considerations in establishing an office-based surgery program.

an environment that fosters interpersonal communication and error management. These goals form the principles of crew resource management. Although the details of implementing a crew resource management program are beyond the scope of this review, basic familiarity with its principles is strongly advised [18–22]. In addition to the medical director, other physicians should be in compliance with the training and competence requirements (Fig. 3).

A physician should attempt OBS only after demonstrating competency in an accredited OR setting. The office is a poor training environment for gynecologists, and can be stressful unless some level of mastery has already been achieved. Relatively simple procedures such as HTO can become demanding if the patient experiences a sudden vasovagal reaction or intolerable pain and anxiety or if the physician encounters severe cervical or tubal stenosis. It is worth noting that procedures generally require some modification once they are brought to the office-setting.

### Anesthesia Considerations

Office-based surgery requires physicians to match the procedure with the analgesic and anesthetic needs of the patient, understanding that patients vary widely in their response to similar stimuli. The ACOG guidelines require that neither safety nor comfort be compromised during OBS procedures. Practitioners are strongly advised to review the ASA guidelines for office-based anesthesia [66] and the Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists [54]. Many physicians underuse parenteral agents because of the false belief that their use is contraindicated for minimal conscious sedation. Use of
moderate conscious sedation or deep sedation carries with it many obligations and responsibilities that vary according to practice location.

**Emergency Transfer Plans**

Physicians must consider the need for an accessible emergency department in an accredited hospital that is temporally convenient and within a reasonable distance from the office should a patient require emergency transfer. A written transfer agreement with a hospital emergency department is advised if not a requirement in your state. Ideally, the physician should have admitting privileges at the hospital that is intended to be used. In addition, a protocol should be developed that specifies the office systems that are activated during an emergency in which a transfer is anticipated.

**Mechanism of Continuous Quality Improvement**

Practices accredited by national agencies are required to developed quality improvement programs. However, all practices should have a mechanism to review unanticipated outcomes. In addition, practices that perform OBS are encouraged to provide individual, team, and system processes to prevent, detect, and mitigate errors before they devolve into an incident or adverse outcome. Powell and Hill [20] suggest a useful approach to these issues, adopting crew resource management techniques in the OR.

**Staff Considerations**

Before considering a list of office-based procedures, the physician and staff must possess a real commitment and enthusiasm for OBS and toward developing a culture of safety, teamwork, and continuous quality improvement. The procedure type, level of sedation, and regulatory requirements will determine the need for the type and number of licensed personnel and their training (basic life support, ACLS, and conscious sedation). Procedure-specific knowledge must be made available by the medical director. In addition, staff competency should be verified and documented. Understanding of the principles of crew resource management is encouraged to create safer and more reliable human performance outcomes.

**Patient Selection**

In transitioning to an OBS setting, one must be selective in choosing the first patients, especially because they do not present themselves in order or increasing complexity. Initial procedures should be limited to women with a calm demeanor and without substantial anatomical abnormalities. Either because of medical contraindications [66], patient anxiety, or anatomical considerations, some women are best treated in a hospital OR. Early success in OBS provides an important positive and reinforcing experience for the physician and the office staff.

**State and Local Zoning Requirements**

Numerous state laws govern OBS (see "Regulations and Policies that Govern OBS Across the United States"). However, various local governments may also establish requirements for OBS or for specific office-based procedures. The physician contemplating instituting an OBS program should also consult local zoning requirements and building codes to determine whether they affect his or her practice.

**Liability**

Medical malpractice insurers should be notified of an OBS practice, including its scope. New York State, for example, will not provide liability coverage for any procedure carried out in an office that is not in compliance with the Department of Health regulations. Any physician's malpractice policy that does not clearly state its applicability to OBS should request a letter from his or her carrier, clearly stating the intent to perform a specific list of procedures, and should request a letter confirming coverage.

**Conclusion**

Although the gynecologic literature traces the origins of OBS to the 1970s, few practitioners have had extensive training or experience operating in the office environment; most have been self-taught. Until the late 1990s, OBS was largely unregulated. The current regulatory environment among state health departments varies substantially; almost half of our states have no requirements for OBS, and the other half vary widely in their regulations. Professional organizations including ACOG, ASA, and several nationally recognized accreditation agencies [67,68] either regulate or provide standards for safe OBS practice.

With the development of procedures that are well suited to the office setting, in an economic environment that often encourages the shift away from the hospital OR or ambulatory surgical center, gynecologists have an ethical responsibility to provide systems, safety, and comfort while maintaining the highest level of skill and professionalism in what can be a daunting environment.

As a specialty, we have at least 3 issues that need to be addressed. First, there is presently no widely accepted national society for OBS that enables physicians to share scientific and clinical information about appropriate procedures and analgesic protocols. Second, we need to provide a mechanism for residency training programs to teach surgery in the office setting. Third, professional societies should consider establishing centers of excellence so that the next generation of providers may be mentored in these new methods.

**References**